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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,804	07/23/2001	Florence Bordon-Pallier	146.1365	9488

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EXAMINER	
MCKELVEY, TERRY ALAN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,804	BORDON-PALLIER ET AL.	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2002 and 02 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/30/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All objections and rejections not repeated in the instant Action have been withdrawn due to applicant's response to the previous Action.

Claim Rejections - 35 USC § 112

Claims 32-34, 36, 39-47, and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record set forth in the paper mailed 8/28/02 (which is extended to new claims as necessitated by the applicant's amendment filed 6/2/04 and modified to take into consideration the new limitations in the claims). Applicants' arguments filed 12/9/02 have been fully considered but they are not deemed to be persuasive.

The claims are drawn to an isolated polynucleotide containing a nucleotide sequence selected from the group consisting of a polynucleotide having at least 50% similarity with a polynucleotide coding for a polypeptide and having an amino acid sequence of sequence SEQ ID NO:3 and having the function of transcription factor thereof, and a DNA sequence as defined in claim 1 wherein this DNA sequence is that of the CAtfIIIA gene coding for a protein having the biological function of transcription factor of C. albicans CATIIIA containing the nucleotide sequence SEQ ID NO:1, and DNA sequences which hybridize with the sequence and/or have a significant homology with this sequence of fragments of it and having the same function, DNA sequence comprising modifications introduced by deletion, insertion and/or substitution of at least one nucleotide coding for a protein having the same biological activity as the transcription factor CATFIIIA, DNA sequences which have a nucleotide sequence homology of at least 50% with the said DNA sequence, DNA sequence which code for a protein with a similar function as the amino acids sequence of which has a homology of at least 50%, with the amnion acid sequence coded by the said DNA sequence. A process, host cell, and kit drawn to the polynucleotides are also claimed. Because of the numerous instances of language in the claims that renders

the claims vague and indefinite, the interpretation of the scope of each of the claims is based upon the examiner's best interpretation of each claim. The polynucleotides and DNA sequences are limited to those that encode a polypeptide that has the function of transcription factor of SEQ ID NO:3 and have some % homology to SEQ ID NO:1 or SEQ ID NO:3.

The product and method claims are genus claims because they comprise the use of polynucleotide and DNA sequences drawn broad range of nucleic acids, related by homology to the nucleic acid sequence or the protein sequence encoded by the nucleotide sequence and encode a protein having the function of transcription factor.

Thus, the claimed polynucleotides and DNA sequences encompass many different nucleic acid sequences having one more nucleotide substitutions, deletions, insertions, and/or additions the polynucleotide set forth by the application: encoding SEQ ID NO:3, limited to those nucleic acids that encode polypeptide that has the transcription factor function of SEQ ID NO:3. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical

properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factors present in the claims are a partial structure in the form of percent identity, further limited a functional limitation drawn transcriptional activity. Beyond the specific description of one protein, which is one C. albicans TFIIIA protein sequence, SEQ ID NO:3, a general description of conserved zinc fingers and serine-rich region (which covers most of the sequence), there is little identification in the specification of all of the particular portions of the structure that must be conserved for the claimed activity. Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus which encompasses the second type of inhibitor.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page

1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polynucleotides encoding the polypeptide set forth as SEQ ID NO:3, but not the full breadth of the claims, meets the written description provision of 35 USC 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Response to Arguments

The applicant's arguments filed 12/9/02 merely are that the amended claims are deemed to be adequately supported by the specification and according to the Examiner. This argument is not persuasive not persuasive because as indicated in the rejection above, the new claims are still drawn to a genus of polynucleotides and that there is only a description of isolated polynucleotides encoding the polypeptide set forth as SEQ ID NO:3.

Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. This rejection is maintained for reasons of record set forth in the paper mailed 8/28/02 (which is extended to new claim 48 as necessitated by the applicant's amendment filed 6/2/04). Applicants' arguments filed 12/9/02 have been fully considered but they are not deemed to be persuasive.

Response to Arguments

The applicant's arguments filed 12/9/02 and 2/10/04 merely indicate that the biological material was deposited in accordance with the Budapest Treaty (and amending the specification to include complete deposit information). However, the required statement concerning the deposit, that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent has not been filed and thus the rejection properly remains of record.

Claim Rejections - 35 USC § 112

Claims 32-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For some of the specific rejections, this rejection is maintained for reasons of record set forth in the paper mailed 8/28/02 (which is extended to new claims as necessitated by the applicant's amendment filed 6/2/04). For other specific rejections, the rejection is new as necessitated by the amendment to the claims filed 6/2/04. Applicants' arguments filed 12/9/02 have been fully considered but they are not deemed to be persuasive.

Regarding claim 32, etc, the use of "polynucleotide having at least 50% similarity with a polynucleotide coding for a polypeptide and having an amino acid sequence of sequence SEQ ID NO:3 and having the function of transcription factor thereof" renders the claims vague and indefinite because it is unclear how the claimed polynucleotide can have an amino acid sequence of sequence SEQ ID NO:3 because polynucleotides may encode amino acid sequences, but cannot "have" them because polynucleotides are not amino acid sequences. Also, it is unclear whether "an amino acid sequence of sequence SEQ ID NO:3 refers to any part of the sequence of SEQ ID NO:3 or only refers to the entire sequence of SEQ ID NO:3. Additionally, it is unclear how a polynucleotide can have the function of transcription factor and whether the function of transcription factor thereof refers to any transcription factor function or only the transcription factor function of SEQ ID NO:3 (i.e., it is unclear to what the "thereof" in the claim refers to).

Regarding claim 33, etc, the dependence of the claims on canceled claims 1, etc renders the claims vague and indefinite because they are dependent on canceled claims. For the purposes of examination and the instant Office Action, it was assumed that the claims refer to claims 32, etc that correspond to canceled claims 1, etc.

Regarding claim 36, etc, the use of "A DNA sequence as defined in claim 1" renders the claims vague and indefinite because claim (32) is drawn to an isolated polynucleotide and not a DNA sequence and thus there is no proper antecedent basis of "A DNA sequence as defined in claim (32)".

Regarding claim 36, etc, the use of "wherein this DNA sequence is that of the CAtfIIIA gene coding for a protein having the biological function of transcription factor of Candida albicans CATIIIA containing the nucleotide sequence SEQ ID NO:1" renders the claims vague and indefinite for the following reasons. It is unclear how a protein having the biological function of C. albicans CATFIIIA (a protein, which is misspelled in the instant new claim) can contain a nucleotide sequence of SEQ ID NO:1. The metes and bounds of what constitutes a "CAtfIIIA" as claimed is also unclear rendering the claims vague and indefinite because the metes and bounds of what is encompassed by this term are unclear. It is entirely unclear how this claim is intended to further limit the isolated polynucleotide of claim (32).

Regarding claims 37, 38, etc, there is no positive antecedent basis for "A DNA sequence according to claim (36)" because the DNA sequence in claim 36 has no positive antecedent basis.

Regarding claim 38, etc, the use of "(413 amino acids)" renders the claim vague and indefinite because SEQ ID NO:3 is a 412 amino acid sequence and thus it is unclear because it is unclear how SEQ ID NO:3 can have 413 amino acids.

Regarding claims 39, 41, 42, etc, the use of "A DNA sequence ... and DNA sequences" and "A DNA sequence ... and a DNA sequence" renders the claims vague and indefinite because it is unclear whether what follows the "and" is intended to be a further limitation of the preamble DNA sequence, or whether what follows are alternative DNA sequences being claimed in the claims. If the former is intended, then the "and" needs to be deleted and the following phrases rewritten to modify the DNA sequence recited in the preamble. If the latter is intended, then the claims need to be rewritten in a Markush format based upon the preamble, which further limits the preamble DNA sequence.

Regarding claim 39, etc, the use of "DNA sequences which hybridize with the sequence and/or have a significant homology with this sequence of fragments of it and having the same function" renders the claim vague and indefinite for the following reasons. "Significant homology" is unclear within this context because there is no clear art recognized definition for this term and the specification sets forth no clear

definition. It is unclear what is meant by "this sequence of fragments of it" because there is no positive antecedent basis for "this sequence of fragments" and "it" within this context is unclear. It is also unclear what constitutes having the same function (and it is unclear which of the alternatives the function applies to).

Regarding claim 40, etc, the use of "at least one nucleotide coding for a protein having the same biological activity" renders the claims vague and indefinite because it is unclear how a nucleotide by itself can code for a protein having the activity as claimed.

Regarding claim 11, etc, the use of "a protein with a similar function as the amino acids sequence of which has a homology of at least 50%, with the amnion acid sequence coded by the said DNA sequence" renders the claims vague and indefinite because the metes and bounds of what constitutes "similar function" are unclear and it is unclear which DNA sequence is referred to "the said DNA sequence" because two different DNA sequences are referred to within the claim. The "amino acids sequence of which" is unclear because it is unclear to what "of which" is referred to what the homology of at least 50% is compared to. Also, what constitutes an amino acid sequence" is unclear.

Regarding claim 43, because the DNA sequence according to claim (36) does not appear to be limited to encoding only protein having the amino acid sequence of SEQ ID NO:3, it is unclear how expression of this DNA sequence results in (only) CATFIIIA having the amino acid sequence of SEQ ID NO:3.

Regarding claim 46, there is no positive antecedent basis for "the host cell" because claim (43) recites "host". Amending claim 43 to recite "host cell" would be remedial.

Regarding claim 49, the use of "functional fragment of this sequence" renders the claim vague and indefinite because it is unclear to what function is being referred.

The phrasing and format of the claims are very unclear for the reasons set forth above. Every attempt was made to identify all specific parts of the claims that render the claims vague and indefinite. Some of these problems are in multiple claims and thus must be corrected in all of the affected claims, even those not specifically identified. However, because of the extreme nature of the problems with the claims, it is possible some problems are masked by other problems, and thus could not be clearly identified.

Response to Arguments

The applicant's arguments filed 12/9/02 and 2/10/04 merely are that the amended claims are that it is believed that the amended claims obviate the rejections and thus the amended claims properly comply with 35 USC 112. This argument is not persuasive because in the cases where the rejection is maintained, the same or substantially the same unclear language still is present in the claims and thus the new claims are vague and indefinite for reasons of record.

Claim Rejections - 35 USC § 102

Claims 32-34, 36, 39-42, 44, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Archambault et al (applicant supplied reference). This rejection is maintained for reasons of record set forth in the paper mailed 8/28/02 (which is extended to new claims as necessitated by the applicant's amendment filed 6/2/04). Applicants' arguments filed 12/9/02 have been fully considered but they are not deemed to be persuasive.

Response to Arguments

The applicant argues that the polynucleotide of Archambault et al encodes an amino acid sequence comprising some groups of 5 amino acids identical to SEQ ID NO:3 but such groups are distributed among the peptide sequence of the present application and all together, the percent homology between the polynucleotide of the reference and the polynucleotide of SEQ ID NO:3 of the present application is only 37% and is excluded from the scope of claim (32) which requires a polynucleotide having at least 50% homology. This argument is not persuasive because claim 32 is drawn to an isolated polynucleotide containing a nucleotide sequence (open language) selected from ... c) a polynucleotide comprising at least 15 consecutive bases of the polynucleotide defined in a) or b). "a)" is drawn to a polynucleotide having at least 50% similarity with a polynucleotide coding for a polypeptide and having an amino acid sequence of sequence SEQ ID NO:3 and having the function of transcription factor thereof. Thus, the claimed polynucleotide encompasses polynucleotides that comprise 15 or more nucleotides that encode the corresponding 5 or more amino acids of the sequence of SEQ ID NO:3 (and polynucleotides that are 50% similar to those polynucleotides). Thus, the claim limitation that the applicant argues that the reference does not teach does

not fully limit the claimed invention because the claims are also drawn to polynucleotides that comprise the claimed fragments, those which hybridize, and those which comprise modifications as claimed.

Claim Rejections - 35 USC § 103

Claims 32-34, 36, 39-47, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Archambault et al (applicant supplied reference) in view of Fujiwara et al (U.S. Patent No. 5,808,030). This rejection is maintained for reasons of record set forth in the paper mailed 8/28/02 (which is extended to new claims as necessitated by the applicant's amendment filed 6/2/04). Applicants' arguments filed 12/9/02 have been fully considered but they are not deemed to be persuasive.

Response to Arguments

The applicant argues that the Archambault et al reference fails for the reason argued above and the citation of Fujiwara et al does not overcome the argued deficiencies. This argument is not persuasive for the same reasons set forth above and thus the instant rejection remains applicable to the new claims and

thus it is proper to maintain the rejection for reasons of record.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify

applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

September 16, 2004

Form PTO-1449

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Docket Number (Optional)	Application Number
146.138	09/831,804
Applicant	
BORDON-PALLIER et al	
Filing Date	**Group Art Unit**
5/8/01	1642 /1636

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation YES	Translation NO
TMc	0 7 0 4 5 2 6	4/96	Europe				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

TMc	1995 Elsevier Science B.V., pgs. 215-218, Drew et al.
	XP-002111350, pgs. 235-238, Arakawa et al, Molecular...factor IIIA
	XP-002130428, 2 pages, 7/25/97 Database EMBL
	XP-002111250, pgs. 1702-1709, Seifart et al, 1/25/89
	XP-002111251, pgs. 20857-20865, Moorefieldt et al, 8/19/94
	XP-000876773, pgs. 167-176, Waldschmidt et al, 11/90

EXAMINER	DATE CONSIDERED
Tanya McKelvey	9/16/04

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

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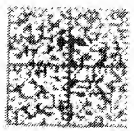

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